

Message Text

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PAGE 01 STATE 256472

61

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 /024 R

66612

DRAFTED BY: DHEW/FDA: LRSHELTON:AMS

APPROVED DY: OES/APT/BMP: MBEAUBIEN

DHEW/OIH: MACODDINGK

EUR/WE: HGMOEN (INFO)

EUR/CE: DANDERSON (INFO)

EUR/WE: WHMARSH (INFO)

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R 292132Z OCT 75

FM SECSTATE WASHDC

TO AMEMBASSY BONN

AMEMBASSY PARIS

AMEMBASSY ROME

UNCLAS STATE 256472

E.O. 11652: N/A

TAGS: OTRA, TBIO, GW, FR, IT

SUBJECT: FDA PROVIDING TECHNICAL CONSULTATION TO DRUG MANUFACTURING PLANTS

1. FDA ADVISES THAT MR. DALE COOPER, SAN FRANCISCO DISTRICT, WILL VISIT SEVEN PHARMACEUTICAL FIRMS IN GERMANY, FRANCE, AND ITALY.
2. THE VISITS WILL BE MADE TO DETERMINE IF THE FIRMS FACILITIES AND CONTROLS ARE IN ACCORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND TO REPORT ANY SIGNIFICANT DEVIATIONS IN THEIR PROCESSES, CONTROLS, OR QUALIFICATIONS OF KEY PERSONNEL WHICH WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY AND EFFICACY OF DRUGS BEING SHIPPED INTO THE U.S.

3. ITINERARY:

NOVEMBER 7 - DEPART WASHINGTON, D.C.

NOVEMBER 8 - ARRIVE BERLIN - HOTEL HILTON

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PAGE 02 STATE 256472

NOVEMBER 10 - VISIT SCHERING AG

NOVEMBER 11 - TRAVEL TO BERGKAMEN
NOVEMBER 12 - VISIT SCHERING-BERGKAMEN
NOVEMBER 14 - TRAVEL TO PARIS
NOVEMBER 17-18 - VISIT ROUSSEL
NOVEMBER 20-21 - VISIT POINTET-GIRARD
NOVEMBER 24 - TRAVEL TO MILAN, HOTEL DE LA VILLE
NOVEMBER 25-26 - VISIT LARK
NOVEMBER 28 - DECEMBER 1 - VISIT INDUSTRIE CHIMICO ITALIANO
DECEMBER 3-4 - VISIT FARMITALIA
DECEMBER 7-8 - VISIT CARLO ERBA
DECEMBER 11 - DEPART FOR U.S.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED.
KISSINGER

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Message Attributes

Automatic Decaptioning: X
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Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Margaret P. Grafeld
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EO Systematic Review
06 JUL 2006

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Status: NATIVE
Subject: FDA PROVIDING TECHNICAL CONSULTATION TO DRUG MANU- FACTURING PLANTS
TAGS: OTRA, TBIO, GE, FR, IT, FDA, (COOPER, DALE)
To: BONN ROME
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006